



# COVID-19 Vaccine - Microplanning

November 12, 2020



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# DISCLAIMER

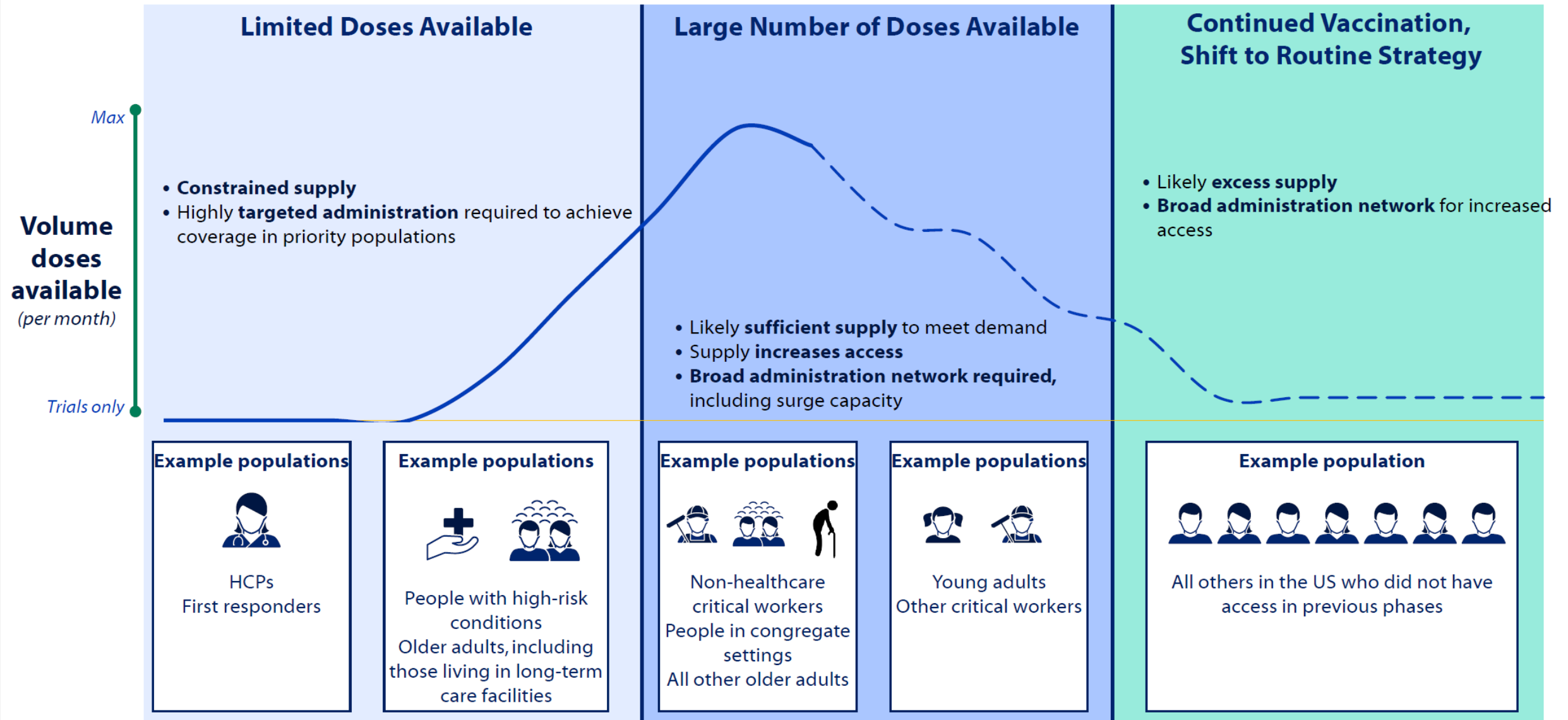
The information presented today is based on CDC's recent guidance and MAY change.

November 12, 2020

# Discussion Topics

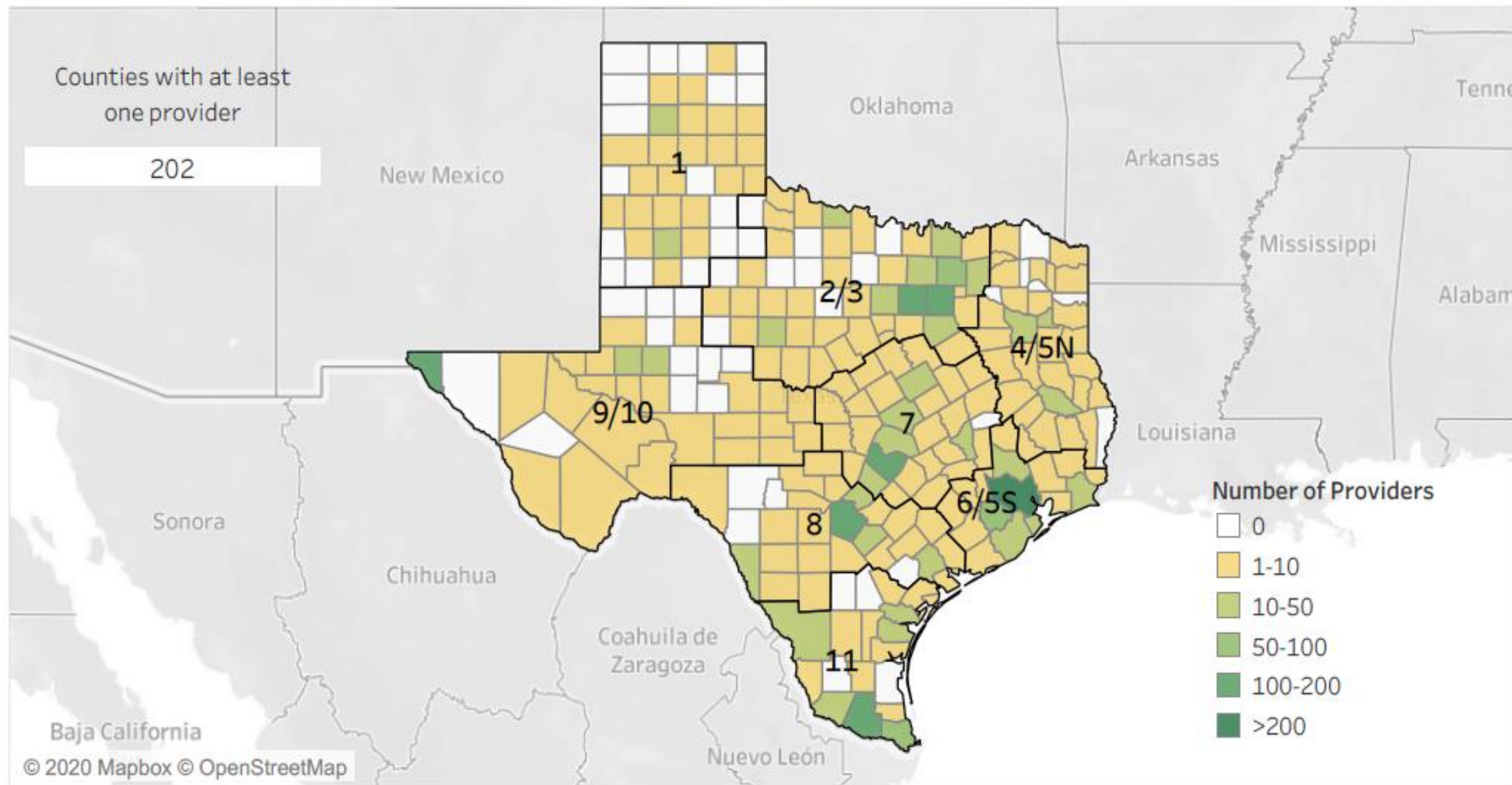
- Opening Remarks
- Vaccine Updates
- Vaccination Microplanning
- Panel Q&A
- Closing Remarks

# Distribution will adjust as volume of vaccine doses increases



Illustrative example populations; final prioritization to be decided by ACIP

# COVID-19 Enrolled Vaccine Providers by County



# COVID-19 Vaccine Vaccination Phased-Approach Overview

- Phase 0 (October 2020-Late November 2020)
- Phase 1 (Late November 2020 – December 2020\*)
  - Limited COVID-19 Vaccine Doses Available
- Phase 2 (January 2021-July 2021\*)
  - Large Number of Doses Available
  - Supply Likely to Meet Demand
- Phase 3 (July 2021 -October 2021\*)
  - Sufficient Supply



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*\*Specific dates are subject to change.*

# Vaccine Updates



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# Evolving Landscape for COVID-19 Vaccine

## Key Assumptions for COVID-19 Vaccine



Limited doses may be available in December 2020, but supply will increase substantially in 2021



Initial supply will either be **approved as a licensed vaccine** or **authorized for use under an EUA** issued by the FDA



**Cold chain storage** and handling requirements are likely to vary from **refrigerated** to **ultra-cold frozen**



**Two doses**, separated by  $\geq 21$  or 28 days, will be **needed for immunity** for most COVID-19 vaccines

# COVID-19 Vaccine Candidates

Manufacturer	Platform	Age Group	Doses needed <sup>2</sup>	Timing	Storage/Handling
Moderna <sup>1</sup>	mRNA	≥18 years	2	0, 28 days	Frozen 7 days refrigerated
Pfizer/BioNTech <sup>1</sup>	mRNA	≥ 12 years	2	0, 21 days	Ultra Cold Frozen 5 days refrigerated
AstraZeneca/Oxford <sup>1</sup>	Non-replicating Viral Vector	≥18 years	2	0, 28 days	Refrigerated
Janssen/Johnson & Johnson <sup>1</sup>	Non-replicating Viral Vector	≥18 years	1	N/A	Frozen 3 months refrigerated
Novavax	Recombinant Protein Subunit	≥18 years	2	0, 21 days	Refrigerated
Sanofi/GSK	Recombinant Protein Subunit	TBD	2	TBD	Refrigerated



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1. Phase 3

2: Intramuscular injection

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Novavax	Recombinant Protein Subunit	≥18 years	2	0, 21 days	Refrigerated
Sanofi/GSK	Recombinant Protein Subunit	TBD	2	TBD	Refrigerated
		1. Phase 3	2: Intramuscular injection		



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# COVID-19 Vaccine Candidates (Moderna & Pfizer)

As of November 9, 2020

		
<b>Presentation</b>	Multidose vials (10 doses/vial)	Multidose vials (5 doses/vial)
<b>Reconstitution</b>	No	Yes, with saline
<b>Dose</b>	100 mcg (0.5mL) IM	30 mcg (0.3mL) IM
<b>2-Dose Series</b>	Day 0 & Day 28	Day 0 & Day 21
<b>Storage</b>	Frozen: 6 months Refrigerator: 7 days Room Temp: 12 hours	Ultra-cold frozen: 6 months Refrigerator: 5 days Room Temp: 6 hours
<b>Minimum Doses Order</b>	100 (10 vials)	975 doses (195 vials)
<b>Availability by end of 2020</b>	~20 Million	~50 Million
<b>Study Status</b>		
<b>Enrollment</b>	Complete (total 30,000) 2 <sup>nd</sup> dose: 25,654	43,538 (total 44,000) 2 <sup>nd</sup> dose: 38,955
<b>Age Groups</b>	≥18 years of age (25%_participants are ≥ 65 years)	<b>≥12 years of age</b> (46%_participants are ages 56-85 years)
<b>Safety Analysis for EUA</b>	Post second dose 2-month median safety data	
	<b>Second half of November</b>	<b>Third week of November</b>
<b>Efficacy for EUA</b>	<b>Interim Analyses #1</b>	
	53 cases (74% VE)	Evaluated 94 cases demonstrate 90% VE



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# Pfizer Vaccine Candidate

Update on Storage, Handling & Administration



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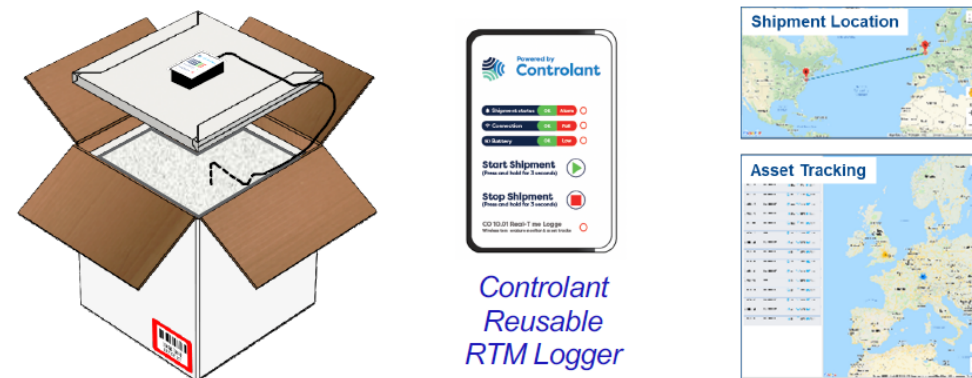
# Direct Shipment to Points of Vaccination

## Direct Shipments\* to Vaccination Center by Transport Courier



Pfizer has designed a distribution model which is built on a flexible just in time system to ship the vaccine from manufacturing site and/or storage facility directly to the points of vaccination.

## Temperature & Location Tracking During Transportation



- Each thermal shipper has reusable GPS enabled temperature monitoring device which will be enabled when the shipper is packed.
- All shipments will be tracked via the onboard GPS monitoring device to ensure end-to-end distribution within required temperatures.
- Shipments will be executed under the management of Pfizer Quality processes and controls to ensure that upon ownership transfer, product has arrived under acceptable conditions.
- Temperature records of the shipments can be shared with upon request.

*Thermal Shippers may have slight differences depending on manufacturer.*

\*COVID Vaccine supply chain model is a drop ship direct from Pfizer manufacturing sites to the designated locations by the governments.  
Markets with no Pfizer commercial legal entity: Product ownership transfer at port of entry for governmental customer importation and in-market distribution



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# Product Packaging Overview



## 1. Primary Packaging



2 mL Type 1 glass  
preservative-free

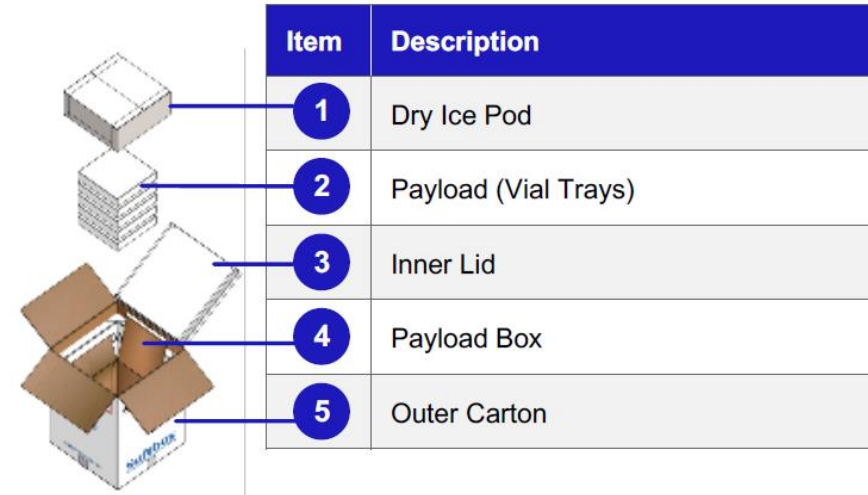
- 2 mL type 1 glass preservative free multi-dose vial (MDV)
- MDV has 0.45 mL frozen liquid drug product
- 5 doses per vial after dilution

## 2. Secondary Packaging “Single Tray”



- Single tray holds 195 vials
- 975 doses per tray
- A smaller tray, containing 25 vials (125 doses) is in development with estimated availability in early 2021

## 3. Tertiary Container: Thermal Shipper



*Thermal Shippers may have slight differences depending on manufacturer.*

- Minimum 1 tray (975 doses) or up to 5 trays (4875 doses) stacked in a payload area of the shipper
- Payload carton submerged in dry ice pellets
- Thermal shipper keeps ULT -75+15°C (-103° to 5°F) up to 10 days if stored at 15°C to 25°C (5° to 77°F) temperatures without opening
- Thermal shippers are reusable and designed to be a temporary storage containers by replenishing dry ice.

# Vaccine Storage Options\* At the Point of Vaccination

1

## Ultra-Low Temperature Freezer

- Store as frozen liquid at  $-75^{\circ}\text{C} \pm 15^{\circ}\text{C}$  for long term storage.
  - Emergency Use vials are labeled as  $-70^{\circ}\text{C} \pm 10^{\circ}\text{C}$ , however they can be safely stored in a freezer set to the USP condition of  $-75^{\circ}\text{C} \pm 15^{\circ}\text{C}$
- Frozen vials at have a 6 month expiry from the date of manufacture
- Different size of ULT freezers are available in the market.

**A small size (under or over the countertop ULT Freezers can store as much as 30K doses)**



2

## Thermal Shipper Designed for Temporary Storage



- Within 24 hours of receipt and after opening the thermal shipper, replenish/inspect with dry ice (using proper personal protective equipment and dry ice handling).
- With every re-icing, thermal shipper can maintain ultra-low temperature storage for 5 days with 2 openings per day.
- Local dry ice suppliers can be used for re-icing the thermal shipper.
- The thermal shipper should be returned within 10 business days and no later than 20 business days including temperature data logger (picked up by Pfizer/BioNTech contracted supplier)
- Apply appropriate dry ice temperature monitor

3

## 2 to 8°C Refrigerator



- Can be stored at 2 to 8°C up to 5 days
- Room temperature storage is no more than 2 hours.
- Thawing: 3 hours at 2 to 8°C or 30 min at room temperature.
- Post-dilution in use period is 6 hours.

\*Product temperature must always be monitored to ensure adherence to temperature requirements for different storage conditions are being met in alignment with site Standard Operating Procedures.

Please note that it is possible that the final preparation and logistical requirements may change in light of forthcoming data on dosing, stability, manufacturing and shipping requirements, but this deck reflects the Company's current understanding based on the totality of available data currently. Current as of September 8, 2020.

# Covid Vx Preparation Instructions

## Supplies Required to Prepare:

- 1 Vial Pfizer BioNTech COVID-19 Vaccine
- 1 Vial 0.9% Sodium Chloride Injection (at least 2 mL)
- 1 diluent syringe/needle (3 mL or 5mL syringe/21 G needle recommended)
- 5 dosing syringes/needles (1 mL syringe/ IM injection needle)
- Other ancillary materials such as alcohol swabs, gloves, PPE



Point Of  
Use (POU)



# Vaccine Preparation and Administration

Point Of  
Use (POU)

## Removing the Vials to Thaw

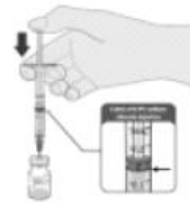


From storage, **remove 1 vial for every 5 recipients** according to planned vaccinations schedule.

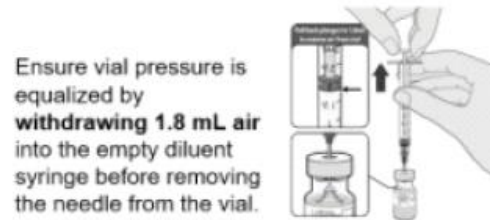
Vials may be stored in the refrigerator for 5 days (120 hours).

## Dilute the Vaccine

Obtain 0.9% Sodium Chloride Injection, USP for use as a diluent. Do not use any alternate diluents.



Dilute the thawed vial by adding **1.8 mL of 0.9% Sodium Chloride Injection** into the vial.

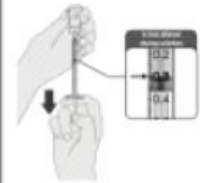


Ensure vial pressure is equalized by **withdrawing 1.8 mL air** into the empty diluent syringe before removing the needle from the vial.

## Preparing the Dose



Draw up **0.3 mL** of the **diluted dosing solution** into a new sterile dosing syringe with a needle appropriate for intramuscular injection.



For each additional dose, use a new sterile syringe and needle and ensure the vial stopper is cleansed with antiseptic before each withdrawal.



## Vaccine Administration



**Pfizer BioNTech  
COVID-19  
Vaccine  
30 mcg/0.3 mL**

Diluted vials must be used within 6 hours from the time of dilution and stored between 2°C to 25°C (35°F to 77°F).

A single 30 mcg/0.3 mL dose followed by a second dose 21 days later.



**21 DAYS**

# Pfizer/BioNTech BNT162b2 Vaccine

- The US Government will be providing dry-ice for first replenishment to each vaccination site
- Vaccination sites will be able to keep and use the GPS enable temperature monitoring device that comes with the thermal shipper.
  - Return the thermal shipper and the GPS temperature monitoring device within 20 business days



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# Vaccination Microplanning

## Pfizer's Vaccine Candidate



# Vaccination Microplanning

- Planning before vaccine arrives
- Vaccine storage conditions most suitable for a site
- Vaccine needs
- Site type
- Staff needs
- Systems validations and reporting
- Ancillary supplies
- Training



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**An Ultra Low Temperature Freezer (ULTF) is the preferred storage option, and is ideal when a Point of Care site...**

- Seeking the preferred storage option which allows for up to 6 months of shelf life
- Is concerned about variability in number of full-time immunizers available and/or variability in patient flow (e.g. walk-ins)
- Is unable to secure dry ice, or meet the handling requirements associated with the use of a thermal shipper as a temporary storage device
- Already has capacity in an existing ultra-low temp freezer (ULTF)

**A Thermal Shipper is ideal when a Point of Care site...**

- Doesn't have access to an ULTF
- Meets all requirements defined in the Pfizer Storage and Handling Guidelines
- Has at least 2 full-time immunizers **and**, is concerned about administering 975 doses in 5 days
- Has consistent and reliable access to dry ice

**A Refrigerator is ideal when a Point of Care site...**

- Has at least 4 full-time immunizers **and**, is expecting to administer at least 975 doses every 5 days
- Is concerned about ordering/ handling dry ice shipments

## Cold Storage Limitations

I

## Ultra-low Temp Freezer (6 months)

## Thermal Shipper (15 days)

I<sup>≡</sup>

## Refrigerator (5 days)

Availability of Full-time Immunizers

No Restriction

Minimum 2 Immunizers

Minimum 4 Immunizers

Anticipated Patient Flow

Minimum 960 Patients in 6 months

Minimum 960 Patients in 15 days

Minimum 960 Patients in 5 days

Allows for Variability in Patient Flow (e.g., walk-ins)

Yes

No

No

Requires Dry Ice Ordering/Handling






No

Yes


Yes

Assumes immunizers are working 8 hours a day, and vaccinating 6 patients an hour

# Site Types for Pfizer Vaccine Candidate

Vaccination site		Ordering assumptions			Operating assumptions				
		Order size	Storage conditions	Patient flow	Number of immunizers	Patients per immunizer	Hours per day	Vaccines per day	Shipment model
	<b>A – large outpatient center (mass vx)</b>	1 tray (975 doses)	Thermal box with dry-ice, 2-8CR fridge, for product estimated at site (5 days)	~500/day	10 immunizers	6 patient/hour (~10 min/Vx)	8 hours	480 vaccinations	1 tray; 2-3 times per week
	<b>B – hospital or outpatient center</b>	1 tray (975 doses)	ULT freezer, Thermal box with dry-ice, 2-8C fridge, for product estimated at site (5 days)	Variable	4 immunizers	6 patient/hour (~10 min/Vx)	8 hours	192 vaccinations	1 tray; every week
	<b>C – large hospital with affiliated outpatient center</b>	5 trays (4,875 doses)	ULT freezer, Thermal box, 2-8C fridge, for product estimated at site (5 days)	Variable	7 immunizers (hospital outpatient clinic)	6 patients/hour (~10 min/Vx)	8 hours	340 vaccinations	1 tray; 1-2 times a week
	<b>D – outdoor parking lot vaccination hub at large retail pharmacy</b>	1 tray (975 doses)	2-8C fridge, for product estimated at site (5 days)	~200/day	5 immunizers	6 patients/hour (~10 min/Vx)	N/A	240 vaccinations	1 tray; every week
	<b>E – mobile vaccination in targeted geographies</b>	5 trays (4,875 doses)	2-8C fridge, for product estimated in mobile unit (5 days)	Variable	3 immunizers	6 patients/hour (~10 min/Vx)	Not specified	150 vaccinations	1 tray; every week

# Site Types for Pfizer Vaccine Candidate

Vaccination site		Order size	Storage conditions	Patient flow	Number of immunizers	Patients per HCP	Hours per day	Vaccines per day	Shipment model
 <b>F – large indoor spaces</b> not used during pandemic (convention hall)		5 trays (4875 doses)	Thermal box with dry-ice, 2-8C fridge, for product estimated at site (5 days)	Variable	10 immunizers	6 patient/hour (~10 min/Vx)	8 hours	480 vaccinations	2-3 trays; Every week
		3 trays (2925 doses)	Thermal box with dry-ice, 2-8C fridge, for product estimated at site (5 days)	Variable	10 immunizers	6 patient/hour (~10 min/Vx)	8 hours	480 vaccinations (by 7 days)	2-3 trays; Every week

# Panel Q&A



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Provider Registration

Vaccine Ordering

Reporting &  
ImmTrac2

Storage & Handling

Training

# Closing Remarks



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# Resources

## **Website for Providers:**

[www.dshs.texas.gov/coronavirus/immunize/provider-information.aspx](http://www.dshs.texas.gov/coronavirus/immunize/provider-information.aspx)

## **FAQ for Providers**

<https://www.dshs.texas.gov/immunize/covid19/COVIDproviderfaq.pdf>

## **DSHS COVID-19 Vaccine Provider hotline:**

(877) 835-7750, 8 a.m. to 5 p.m., Monday through Friday or

Email: [COVID19VacEnroll@dshs.texas.gov](mailto:COVID19VacEnroll@dshs.texas.gov).

## **Website to enroll as a COVID-19 provider:**

[EnrollTexasID.dshs.texas.gov](http://EnrollTexasID.dshs.texas.gov).

## **General Questions:**

Email: [COVIDvaccineQs@dshs.texas.gov](mailto:COVIDvaccineQs@dshs.texas.gov)